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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,310	04/29/2005	Kaoru Okakura	Q87626	2360

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EXAMINER

CHOWDHURY, IQBAL HOSSAIN

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

10

Office Action Summary	Application No. 10/533,310	Applicant(s) OKAKURA ET AL.	
	Examiner Iqbal H. Chowdhury, Ph.D.	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 10 and 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 10 and 11 is/are rejected.
- 7) ☒ Claim(s) 2-3 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

In response to a previous Office action, a non-final requirement (mailed on 4/1/2006), Applicants filed a response and amendment received on July 10, 2006. Claims 1-6 and 9-21 are amended and claims 4-9, and 12-21 are withdrawn. Thus, Claims 1-3, and 10-11 are pending in the instant Office action and will be examined herein.

Applicants' arguments filed on July 10, 2006, have been fully considered but are not deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Regarding lack of unity, which was made **FINAL** in the previous office action, the applicants again argue stating that because claim 1 is amended by deleting "one or plural amino acids are added to or deleted from N-terminus of the amino acid sequence of SEQ ID NO: 1", that SEQ ID NO: 1 is linking feature of all the claims, to rejoin i.e. all the claims which are dependent on claim 1 should be rejoined and claiming that lack of unity no more exists. This is not found persuasive because such amendment does not change core point that a polypeptide comprising SEQ ID NO: 1 with a "a plurality of amino acids deleted from the N-terminus of said polypeptide (part (e)) i.e. more than one amino acids deleted from the N-terminus of said polypeptide and SEQ ID NO: 1" results in the lack of specific structure of the claimed polypeptide, which could be a protein comprising any fragment of SEQ ID NO: 1, and such a protein and fragments are disclosed in WO01/90375, which is therefore, known in the art.

For the reasons above and as discussed in length in the previous office action, the requirement is maintained.

Maintained-Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Previous rejection of Claims 1 and 10-11 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection has been described in length in previous Office Actions. Applicant's amendments and arguments have been fully considered but are not deemed persuasive for the following reasons.

Claim 1, an independent claim, is directed to a genus of a modified or variant polypeptide molecule having "a plurality of amino acids deleted from the N-terminus of said polypeptide (part (e)) i.e. more than one amino acids deleted from the N-terminus of said polypeptide.

Applicants argue that at page 5, lines 24-32, of the specification, it is stated that the cellulases of the present application include the polypeptide of SEQ ID NO: 1, as well as those polypeptides having one or a plurality of amino acids added to or deleted from the N-terminus of the polypeptide of SEQ ID NO: 1 and as explained in this section of the specification, the cellulases of the present application may include a secretory signal sequence that undergoes differential processing, depending on the bacterial host used to produce the cellulase. Therefore, homologous proteins having an amino acid sequence in which one or plural amino acids are added to or deleted from the N-terminus of the polypeptide of SEQ ID NO: 1 are included within

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the scope of the present invention. Applicants further argue that when a secretory protein, such as a cellulase, is produced using genetic engineering techniques, a host is generally transformed with an expression vector containing a DNA encoding a precursor of the secretory protein. The precursor is composed of a mature protein portion, and a secretory signal sequence attached to the N-terminus of the mature protein portion and when the precursor expressed in the host is secreted from the host, the secretory signal sequence is removed from the precursor by a signal peptidase to convert the precursor into a mature protein. Applicants further state that it is well-known for those skilled in the art that a secretory signal sequence is sometimes processed differently, depending on the host used for the production, and thus one or a plurality of amino acids may be added to or deleted from the N-terminus of a mature protein and in view of the noted support in the specification, included herewith is an amendment to claim 1 such that the claims now recite a small, well-defined genus of polypeptides. The skilled artisan would have recognized that Applicants were in possession of the recited genus of polypeptides at the time the application was filed. Applicants finally concluded by stating that the claims thus have adequate written description support in the application as filed, and request reconsideration and withdrawal of this rejection.

Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection of claims 1 and 10-11. The examiner acknowledges the amendment to the claim 1 by adding substitution at positions 162 and/or 166 but disagrees with the applicant's contention that the claimed invention is adequately described. Claim 1 still reads on a genus of modified or variant polypeptide molecules having "a plurality of amino acids deleted from the N-terminus of said polypeptide (part (e)) i.e. more than one amino acids deleted from the N-

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terminus of the polypeptide of SEQ ID NO: 1 having the recited mutations. Applicants have not specified how many amino acid residues are deleted from N-terminus of the mutants of SEQ ID NO: 1 and what is the resulting fragment of protein? Does the fragment comprise any enzymatic activity? Therefore, claim 1 lacks of structure of the claimed genus and function as well. Therefore, claim 1 and all the dependent claims lack appropriate written description and therefore, the rejection is maintained as described in the previous office action and discussed above.

Previous rejection of claims 1 and 10-11 under 35 U.S.C. § 112, first paragraph, as failing to comply with enablement requirement, is maintained. This rejection has been described in length in previous Office Actions. Applicant's amendments and arguments have been fully considered but are not deemed persuasive for the following reasons.

As mentioned in the previous office action, Claim 1 is so broad as to encompass a genus of modified protein molecule having a plurality of amino acids deleted from the N-terminus of said polypeptide (part (e)) i.e. more than one amino acids are deleted from the N-terminus of the polypeptide of SEQ ID NO: 1 having the specific recited mutations.

Applicants argue that the pending claims have been amended to recite a small, well-defined genus of polypeptides. Applicants further note that a signal peptide for secretion (i.e., secretory signal sequence) and a host which may be used in the production of the polypeptides recited in the claims are disclosed on page 9, lines 1-5 and page 9, lines 11-16 of the specification, respectively. Applicants further assert that there is sufficient guidance to enable

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one of ordinary skill in the art to make and use the polypeptides as recited in the amended claims. Accordingly, Applicants request reconsideration and withdrawal of this rejection.

Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection of claims 1 and 10-11. The examiner acknowledges the amendment to the claim 1 but disagrees with the applicant's contention that the claimed invention is enabled for full scope claimed.

The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of mutants due to a plurality of amino acids deleted from the N-terminus of the specific mutant polypeptide of SEQ ID NO: 1 broadly encompassed by the claims. The scope of the claimed invention is still broad in the context of "any plurality of amino acids deleted from the N-terminus of the amino acid sequence of specific mutants of SEQ ID NO: 1.

While a polypeptide or its variants of a known sequence by using deletion mutagenesis is well known in the art and producing variants as claimed by applicants, that requires, one of ordinary skill in the art know or be provided with guidance for the selection of which of the infinite number of variants due to deletion mutation, have the claimed property. With only the limited guidance provided by the specification and one of ordinary skill would be reduced to the necessity of producing and testing virtually all of the possibilities. This would clearly constitute **undue** experimentation. The specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. Such guidance has **not** been provided in the instant specification.

For all the reasons above, the examiner finds that amendment of claim 1 does not describe the structural features of claimed genus in sufficient detail to overcome the rejection. Therefore, for the reasons above, the rejection is maintained.

Maintained-Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Previous rejection of Claims 1 and 10-11 under 35 U.S.C. 102(b) as being anticipated by Murashima et al. (WO01/90375, publication date 11/29/2001, see IDS, citation #1 of 4/29/2005) is maintained. Applicants argue that each of the pending claims is directed to a polypeptide having at least one of two substitutions (at amino acids 162 and 166 of SEQ ID NO: 1) and the polypeptide of Murashima does not include either of the two recited substitutions. Applicants also argue that Murashima thus does not teach each and every limitation of the amended claims and accordingly, Murashima does not anticipate the amended claims. Further, Applicants request reconsideration and withdrawal of this rejection.

Applicant's arguments have been considered but are not deemed persuasive to overcome the rejection. As discussed previously, Murashima et al. disclose the sequence of a modified protein (SEQ ID NO: 1) having 223 amino acids residues, which is 100% identical to SEQ ID NO: 1 and 98.8% identical to the SEQ ID NO: 3 (only difference in 162nd and 166th positions of the amino acid sequence) of the instant application, having endoglucanase or cellulase activity. As part (e) of claim 1 of the instant application, which recites "a plurality of amino acids deleted

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from the N-terminus of the polypeptide” i.e. more than one amino acids deleted from the N-terminus of the polypeptide of SEQ ID NO: 1 having recited mutations and such a deletion at the N-terminus results in a protein structure, which may or may not have the specific function. The SEQ ID NO: 1 (polypeptide) of Murashima et al. from position 167-223 is 100% identical to position 167-223 of SEQ ID NO: 3 of the instant application (part (e)), having plurality of amino acids deleted from N-terminus, similar to a polypeptide (SEQ ID NO: 3) having plurality of amino acids deleted from N-terminus of the instant application as claimed (part (e)). Therefore, the polypeptide comprising the fragment of Murashima et al. is within the scope of the modified polypeptide having N-terminus deletion of instant application as claimed (part (e)). Therefore, the rejection is maintained as discussed.

Summary of Pending Issues

The following is a summary of the issues pending in the instant application:

Claims 1-3, 6, 21-22 and 45-48 stand rejected under 35 U.S.C. § 112 first and 102(b).

Claims 2-3 are objected to as depend on rejected claim.

Conclusion

Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution. **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

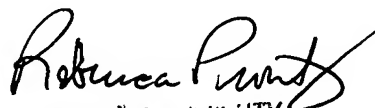
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury, Ph.D. whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

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